Introduction

Transplantation is the procedure involving the removal of a bodily organ or tissue from one person, and the insertion of that organ or tissue into another person to replace a damaged organ or tissue.

Definition of Terms:
Allograft – transplant from one individual to another (synonymous with homograft)
Hereotopic graft – transplant placed in a site different than the organ's normal location
Orthotopic graft – transplant placed in its normal anatomical site
Syngeneic graft (isograft) – transplant between identical twins
Xenograft – transplant between different species

Organ transplantation is now well established as an effective treatment for selected patients with end-stage organ failure. Transplantation of the kidney, liver, pancreas, heart, and lungs are all routine procedures, and transplantation of the small intestine is becoming more widely practiced. Currently, transplant activity is limited only by the shortage of cadaveric organs.

The following policy contains the minimal criteria for solid organ transplants. Additional justification may be required at the discretion of the Division of Medical Assistance Hospital Consultant staff.

1.0 Definition of the Procedure

Islet cells are extracted from a donor's pancreas and injected into a recipient's liver. Islet cell transplantation requires immunosuppressive drugs, which induce diabetes.

2.0 Eligible Recipients

2.1 General Provisions

Medicaid eligible individuals with a need for this specialized treatment confirmed by a licensed physician are eligible as long as they meet individual eligibility requirements. Medicaid recipients may have service restrictions due to their eligibility category, which would make them ineligible for this service.

2.2 Special Provisions

Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) is a federal Medicaid requirement that provides recipients under the age of 21 with medically necessary health care to correct or ameliorate a defect, physical or mental illness or a condition identified through a screening examination. While there is no requirement that the service, product or procedure be included in the State Medicaid Plan, it must be listed in the federal law at 42 U.S.C. § 1396d(a). Service limitations on scope, amount or frequency described in this coverage policy do not apply if the product, service or procedure is medically necessary.

The Division of Medical Assistance's policy instructions pertaining to EPSDT are available online at http://www.dhhs.state.nc.us/dma/prov.htm.

3.0 When the Procedure is Covered

The N.C. Medicaid program covers autologous islet cell transplantation as an adjunct to total or near total pancreatectomy in patients with chronic pancreatitis only.

Each recipient's condition is evaluated on an individual basis. There may be other conditions that are indications for non-coverage.

4.0 When the Procedure is Not Covered

Islet cell transplantation is not covered when the medical necessity criteria listed in **Section 3.0** are not met. Each recipient's condition is evaluated on an individual basis. There may be other conditions that are indications for non-coverage.

4.1 Allogeneic or Xeno Islet Cell Transplantation

The N.C. Medicaid program **does not cover** allogeneic or xeno islet cell transplantation for any diagnosis.

4.2 Psychosocial History

Islet cell transplantation is not covered when the recipient's psychosocial history limits the recipient's ability to comply with pre- and post-transplant medical care.

4.3 Medical Compliance

Current patient and/or caretaker non-compliance that would make compliance with a disciplined medical regime improbable

4.4 Substance Abuse

Islet cell transplantation is not covered when the recipient has an active substance abuse or, for recipients with a history of substance abuse, there is no documentation of the completion of a substance abuse and/or therapy program plus six months of negative sequential random drug screens.

Note: To satisfy the requirement for sequential testing as designated in this policy, the Division of Medical Assistance (DMA) must receive a series of test (alcohol and drug) results spanning a minimum six-month period, allowing no fewer than a three-week interval and no more than six-week interval between each test during the given time period. A complete clinical packet for prior approval must include at least one documented test performed within one month of the date of request to be considered.

4.5 Donors

Living donor expenses **are not covered** for islet cell transplants.

5.0 Requirements for and Limitations on Coverage

All applicable N.C. Medicaid policies and procedures must be followed in addition to the ones listed in this procedure.

All procedures must be prior approved by DMA.

6.0 Providers Eligible to Bill for the Procedure

Physicians enrolled in the N.C. Medicaid program who perform this procedure may bill for this service.

7.0 Additional Requirements

FDA approved procedures, products, and devices for implantation must be utilized.

Implants, products, and devices must be used in accordance with all FDA requirements current at the time of surgery.

A statement signed by the surgeon certifying all FDA requirements for the implants, products, and devices must be retained in the recipient's medical record and made available for review upon request.

8.0 Policy Implementation/Revision Information

Original Effective Date: January 1, 1994

Revision Information:

Date	Section Revised	Change
7/1/05	Entire Policy	Policy was updated to include coverage criteria effective with approved date of State Plan amendment 4/1/05.
9/1/05	Section 2.2	The special provision related to EPSDT was revised.
12/1/05	Section 2.2	The web address for DMA's EDPST policy instructions was added to this section.

Attachment A
Claims Related Information

Reimbursement requires compliance with all Medicaid guidelines including obtaining appropriate referrals for recipients enrolled in the Medicaid Managed Care programs.

A. Claim Type

1. Physicians bill professional services on the CMS-1500 claim form.
2. Hospitals bill for services on the UB-92 claim form.

B. Diagnosis Codes that Support Medical Necessity

Providers must bill the ICD-9-CM diagnosis code to the highest level of specificity that supports medical necessity.

C. Procedure Codes

Codes that are covered under the islet cell transplantation include: 48160 and S2102

D. Providers must bill their usual and customary charges.